K03 1567

OCT - 2 2003

CSIST

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

July 25, 2003

Submitter's Information: 21 CFR 807.92(a)(1)

CHUNG-SHAN INSTITUTE OF SCIENCE AND TECHNOLOGY
481 CHIA-AN SEC. CHUNG-CHENG RD.
LUNG-TAN, TAO-YUAN, CHINA (TAIWAN) 32500

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	3D inVIVO™ by CSIST
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050
Name:	System, Image Processing

Predicate Device: 21 CFR 807. 92(a)(3)

Device Classification Name	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
Regulation Number	892.2050
510(k) Number	K030635
Device Name	THE OBSIDIAN PACS SYSTEM
Applicant	OBSIDIAN MEDICAL TECHNOLOGY, INC. 5108 CORONA CT. PLEASANTON, CA 94588
Contact	BIANCA GREEN
Product Code	LLZ
Decision Date	03/28/2003

Device Description: 21 CFR 807 92(a)(4)

The CSIST 3D inVIVO™ interactive 3D diagnostic ultrasound system (3DUS) acquires a set of successive 2D ultrasound images from Ultrasound system and coverts them into a 3D ultrasound image, stores the 3DUS images in the Image Archive of DICOM Image Server, views patient data and medical images via the Intranet or Internet, supplies image availability information to the Department System Scheduler/Order Filler with DICOM 3.x standard, and accept schedule information and updated procedure information from the Department System Scheduler/Order Filler with HL7 version 2.4 standard.

CSIST Interactive 3DUS system is a PC-based Modality with operating system of MS Windows NT/2000/XP. 3D inVIVO™ provides the advanced process functions, such as :

- Supports the freehand scanning, 3D image acquisition, and 3D reconstruction.
- Acquires images from ultrasound system in real time.
- Supports the ultrasound image storage and ultrasound multi-frame image storage.
- Converts non-DICOM to DICOM format.
- Supports the GUI functions: zoom, pan, pseudo-color setting, threshold setting, Gamma correction, and thumbnail.
- Provides the DICOM query and retrieve services (images and presentation states).
- Displays the cut planes of 3D image along the long axis or the short axis.
- Provides 3D rendering modes: MIP, X-ray, translucent, surface, slicing, and 3D cine.
- Supports distance/area/angle measurements.
- Supports Tele-medicine (audio, video, and text) between regional medicine center and remote clients.

Indications for Use: 21 CFR 807 92(a)(5)

3D inVIVO™ is a PACS System used to acquire, transmit, view, and store image or patient data. This data can be transmitted, stored, and viewed over a computer network or off-site using an Internet connection. The typical users of this system are trained professionals including radiologist, physicians, technicians, and nurses.

The 3D inVIVO™ is indicated for capture and storage of 2D images from ultrasound systems and reconstructing them into 3D ultrasound images. These images provide an approximate representation of the 3D volume and are not intended for use in diagnosis or quantitative measurements.

Technological Characteristics: 21 CFR 807 92(a)(6)

The device is a software application and does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for 3D inVIVO™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. 3D inVIVO™ will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.
The submission contains the results of a hazard analysis and the potential hazards have been classified as Minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2003

Chung-Shan Institute of Science and Technology
c/o Mr. Carl Alletto
1100 Lakeview Blvd.
DENTON TX 76208

Re: K031567
Trade/Device Name: 3D inVIVO™ by CSIST
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: July 26, 2003
Received: July 28, 2003

Dear Mr. Aletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

CSIST

(Indications for Use Form)

510(k) Number: K031567

Device Name:

CSIST Interactive 3D Diagnostic Ultrasound System called "3D inVIVO™.

Indications for Use:

3D inVIVO™ is a PACS System used to acquire, transmit, view, and store image or patient data. This data can be transmitted, stored, and viewed over a computer network or off-site using an Internet connection. The typical users of this system are trained professionals including radiologist, physicians, technicians, and nurses.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031567